REMARKS

Claims 82-91 presently appear in this case. No claims have been allowed. The Official Action of May 20, 2010, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method for the treatment of an ear disorder in a subject in need of such treatment. The treatment comprises administering into the ear canal of the subject a pharmaceutical agent known to affect an ear disorder, in the form of foam or a mousse. The invention also relates to a dispensing device for dispensing medication to the ear. The dispensing device includes a container containing a medication formulation comprising a medication known to affect an ear disorder, in such a manner that, when the medication formulation is dispensed from the container, it is dispensed in the form of a foam or mousse. The device also includes a pipe that extends from the container and that allows access of the foam or mousse to the ear.

Claim 54, 65-67, 75 and 77 have been objected to as including improper Markush language. Claim 76 has been objected to in view of a missing comma.

Claims 54, 65-67, 75 and 77 have all now been deleted, without prejudice. The specified grounds of

objection are no longer applicable to any of the presently pending claims. Accordingly, this objection has now been obviated.

Claims 76 and 78-81 have been rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement insofar as they refer to "derivatives."

Claims 76 and 78-81 have now been deleted, without prejudice. The term to which the examiner objects no longer appears in any of the new claims. Accordingly, this rejection has now been obviated.

Claims 24 and 29 have been rejected under 35 USC 102(e) as being anticipated by Tamarkin. This rejection is respectfully traversed.

The invention of Tamarkin relates to the particular ingredients of the foam disclosed therein, not to any unobvious advantages in using it to apply medications to the ear canal. However, the examiner relies on Tamarkin specifically for its disclosure of use of foam in the ear canal.

Tamarkin is the publication of a U.S. patent application that was filed on April 28, 2004, and is based on two provisional applications, 60/530,015, filed on December 16, 2003, and 60/492,385, filed on August 4, 2003. Copies of

each of these priority applications are submitted herewith. The earliest provisional application of Tamarkin, filed on August 4, 2003, discloses nothing whatsoever about administering to the ear canal. The only cavities specifically mentioned are the oral cavity, rectum and vagina (see page 16, first paragraph, page 17, second paragraph, page 22, first paragraph, and page 42, claim 12, of Tamarkin provisional application of August 4, 2003). It also discloses administering the foam to the skin, for example for the treatment of dermatological disorders (see page 12 of Tamarkin provisional application of August 4, 2003). There is nothing in the Tamarkin provisional application of August 4, 2003, that discloses use in the ear or the advantages of using a foam to administer a medication to the ear. Thus, the disclosure of Tamarkin about use of a foam in the ear canal does not have an effective filing date of August 4, 2003.

The earliest disclosure of Tamarkin relating to use in the ear canal is in the December 16, 2003 (see page 34, penultimate paragraph, of Tamarkin provisional application of December 16, 2003), provisional application. Thus, the earliest effective date as a reference for the disclosure of use of a foam in the ear canal in Tamarkin is December 16, 2003. See MPEP 2136.03, where it states:

> The 35 U.S.C. 102(e) critical reference date of … U.S. application publications …

> entitled to the benefit of the filing date of a provisional application under 35 U.S.C. 119(e) is the filing date of the provisional application with certain exceptions **if** the provisional application(s) properly supports the subject matter relied upon to make the rejection in compliance with 35 U.S.C. 112, first paragraph. [emphasis original]

The present application claims priority of a provisional application filed on December 12, 2003, application no. 60/530,014. The present claims have now been rewritten in language that is clearly supported by this December 12, 2003, provisional application. Accordingly, the effective filing date for each of the present claims is December 12, 2003, which antedates the first disclosure of Tamarkin relating to the use of foam in the ear canal. The following chart shows how the subject matter of the present claims is supported by the December 12, 2003, priority application.

Claims	Application 60/530,014
82 A method for the treatment of an ear disorder in a subject in need of such treatment, the method comprising the step of:	See the only full paragraph on page 1, "a new and useful treatment of ear disorders"
administering into the ear canal of the subject	Page 5, first sentence
a pharmaceutical agent known to affect an ear disorder,	Page 2, first sentence, "compounds known to treat ear disorders"
the pharmaceutical agent being administered in the form of a foam or a mousse	Page 5, second sentence, "the medication is inserted in the form of a foam or a mousse."

83. The method according to claim 82, wherein the administering step is accomplished by ejecting the foam or mouse into the ear canal from a dispensing device	Last paragraph on page 5, describing a device which, when pressed, "the medication is ejected in the form of mouss[sic] or foam."
84. The method according to claim 83, wherein the dispensing device includes a container and	See last paragraph of page 5, which describes a container as one of the two parts of the device.
a pipe that extends from the container and allows access of the foam or mousse to the ear.	See the last sentence on page 5
85. The method according to claim 82, wherein said dispensing device is pressurized.	Page 5, last paragraph, first sentence, where it states that the medication "shall be packed under pressure"
86. The method according to claim 82, wherein the at least one pharmaceutically active agent is selected from the group consisting of an antibiotic agent, an antibacterial agent, an antifungal agent, a steroid agent,	Page 5, lines 14-15, "any other antibiotic/ antibacterial/ anti-fungal and/or steroid derivate …"
an analgesic agent	Page 5, line 20, "analgesic"
and a mixture thereof.	Page 5, second and third paragraphs
87. The method according to claim 82, wherein the ear disorder is acute otitis externa or otalgia.	Page 5, first sentence.

88. The method according to claim 82, wherein the at least one pharmaceutically active agent is selected from the group consisting of neomycin, polymyxin B, ciprofloxacin, ofloxacin, oxytetracycline, nystatin colistin sulfate, hydrocortisone, betamethasone dexamethasone, benzocaine, amethocaine, and tetracaine.	Page 5, lines 11-22.
89. The method according to claim 82, wherein said administering step comprises administering the mousse or foam only once or twice a day.	Page 5, lines 7-10, "allows non-frequent applications (e.g. once or twice a day)…"
90. A dispensing device for dispensing medication to the ear, comprising:	Page 1, first paragraph, and page 5, last paragraph.
a container containing a medication formulation comprising a medication known to affect an ear disorder, in such a manner that, when the medication formulation is dispensed from the container, it is dispensed in the form of a foam or mousse; and	Page 5, last paragraph, "one is the container which contain the medication formulation, when pressed the medication is ejected in the form of mousse [sic] or foam."
a pipe that extends from the container and that allows access of the foam or mousse to the ear.	Page 5, last sentence, and Drawing 1 on page 7.
91. The dispensing device in accordance with claim 89, wherein the medication formulation is packed in the container under pressure.	Page 5, last paragraph, "shall be packed under pressure …"

As all of the present claims are fully supported by applicant's December 12, 2003, priority application, this antedates the Tamarkin application which, insofar as its

disclosure of use of foam in the ear canal is concerned, is only entitled to an effective date as a reference of December 16, 2003. Reconsideration and withdrawal of this rejection is therefore respectfully urged.

Claims 40, 43, 45, 54 and 64-81 have been rejected under 35 USC 103(a) as being unpatentable over Tamarkin. The examiner states that Tamarkin teaches foam compositions useful for the treatment and prevention of disorders and diseases of body cavities such as the ear canal. The examiner concedes that Tamarkin does not have any specific disclosure on treating a disorder of the ear and a device comprising an extension extending from the container. However, the examiner considers that it would have been obvious to have modified the teachings of Tamarkin to arrive at the claimed invention because Tamarkin discloses a foam formulation intended for use in a body cavity, such as the ear, for treating disorders. This rejection is respectfully traversed.

As with the anticipation rejection, it is important for the examiner to rely on the feature of Tamarkin that the foam may be used in the ear canal. However, as this feature is not in Tamarkin's provisional application of August 4, 2003, the earliest effective filing date for the subject matter relied upon to make the rejection is December 16, 2003. As all of the present claims have been shown above to be

supported by applicant's provisional application of December 12, 2003, from which it claims benefit, Tamarkin has been antedated and is not available as a reference. Reconsideration and withdrawal of this rejection are therefore respectfully urged.

Claims 24, 29, 40, 43, 45, 54 and 64-81 have been rejected under 35 USC 103(a) as being unpatentable over Abram in view of Purwar. The examiner states that Abram teaches a pharmaceutical aerosol foam composition for the topical delivery of pharmaceutical active ingredients, which foam composition includes active agents such as analgesics, antifungals, antibacterials, etc. The examiner concedes that Abram does not disclose dispensing such a foam into the external auditory meatus. The examiner states that Purwar teaches a method of treating otitis by introducing an antibacterially effective amount of a non-toxic topical otic pharmaceutical composition. The examiner considers it obvious to have combined the teachings of Abram and Purwar so as to prepare a foam formulation for the easy delivery of an active agent to the ear canal. The examiner states that while Abram does not specifically teach administration of the foam formulation to the ear canal, it would have been obvious to deduce such from the combined teachings because Abram teaches foam formulations comprising an active agent delivered

topically and Purwar discloses topical formulations comprising an active agent delivered to the ear canal. The examiner further states that, although neither reference teaches a dispensing device containing an extension, Abram teaches a spray device for delivering its foam formulations and it would have been obvious to employ a suitable delivery device or to modify the device to adjust for ear canal delivery. This rejection is respectfully traversed.

Abram teaches topical administration to the skin of a foam carrying an active ingredient. Purwar teaches a standard mode of delivery to the ear using ear drops or cotton wick. See column 3, lines 61-63, column 5, lines 9-14, column 10, lines 59-61, and column 13, lines 42-44, of Purwar. Thus, the examiner contends that a *prima facie* case of obviousness has been made out. It is urged, however, that there is nothing in the prior art of record that makes obvious the substantial advantages one achieves when administering a foam to the ear in place of ear drops, which advantages would not have been obvious from any of the advantages known for the topical administration of a foam or mousse to the skin with an active ingredient.

There are significant indicia of unobviousness of the present invention because the present invention solves a long sought need as to how to medicate the ear. As explained

in the present specification, there are significant problems when applying ear drops. First, the liquid will tend to leak out of the ear if the patient receives the drops while the head is upright and, accordingly, the patient has to lay down when the medicine is taken or the head must be substantially tilted. This problem is solved when using a foam. It is a much easier and more comfortable way of administering the medication to the ear. In addition, a foam will hold the medication in contact with the ear over a longer period of time, as opposed to the simple use of ear drops as with Purwar. Another disadvantage of the ear drops of Purwar is that a liquid medication can often cause hearing problems, whereas this problem is avoided for the most part when using a foam.

Additional advantages of using foam for the treatment of ear disorders are listed in paragraphs [0031], [0079], and [0080] of the publication of the present application. For example, one can achieve uniform distribution of the formulation in the ear canal when using a foam. Furthermore, the foam formulation evaporates spontaneously out of the ear without dripping. Use of a foam will readily allow a measured dosage of the formulation. Also, use of a foam allows prolonged contact of the active agent with the ear canal, which enables non-frequent

applications. Furthermore, there is no need of a cotton-wool plug or ear wick in the ear meatus, thus improving compliancy. None of these advantages would have been obvious to one of ordinary skill in the art at the time the present invention was made. Certainly, none of them are explicitly taught or suggested by anything in Abram or Purwar or any combination thereof.

Only hindsight considerations can allegedly make obvious the substantial and unique advantages that one obtains only when using a foam composition in the ear canal. But the leading Supreme Court case on obviousness is very explicit that hindsight must be avoided. See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421, 82 USPQ2d 1385, 1397 (2007) where it states:

> A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.

Despite the fact that topical foams have been known for decades and ear drops have been known for even longer, there is not a single reference where anyone has applied an ear medication in the form of foam or mousse by spraying the foam into the ear canal. The fact that no one has done this before is further evidence rebutting any hindsight analysis that the advantages of doing so would have been obvious.

For all of these reasons, reconsideration and withdrawal of this rejection are respectfully urged.

Claims 24, 40, 43, 54, 64-68, 71, 73-76 and 78 have been rejected under 35 USC 103(a) as being unpatentable over Klein in view of Purwar. The examiner states that Klein teaches topical or local application comprising at least one corticosteroid which can be administered in the form of a foam. The examiner states that Klein discloses that local application means use in body cavities such as those including mucus membranes, i.e., vaginal, nasal, anal, etc. The examiner concedes that Klein does not disclose administration to the ear or the use of a dispensing device adapted for dispensing the composition into the ear canal. The examiner relies on Purwar for supplying these deficiencies for the same reasons as discussed in the previous rejection. This rejection is respectfully traversed.

Klein adds nothing to the deficiencies of Abram discussed with respect to the previous rejection and thus the present claims as a whole are unobvious for the same reasons as discussed above with respect to the Abram/Purwar rejection. While Klein speaks of application to body cavities including mucous membranes, such as vaginal, nasal, anal, etc., it is very telling that it does not include reference to the ear canal. If it were obvious to apply the foam to the ear canal,

it certainly would have been listed among the "body cavities." There is no suggestion in Klein or in any combination of Klein with Purwar that replacing ear drops with a medicated foam when applying to the ear can solve so many problems and have such great advantages as discussed in detail above with respect to the previous rejection. Accordingly, no combination of Klein with Purwar can make obvious the present invention as a whole, including the unique advantages of the combination discussed in detail above and in the present specification. Accordingly, this rejection must be withdrawn for the same reasons as discussed in detail hereinabove with respect to the Abram/Purwar rejection. Reconsideration and withdrawal of this rejection are therefore respectfully urged.

It is submitted that all of the claims now present in the case clearly define over the references of record and fully comply with 35 USC 112. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant

By /rlb/
Roger L. Browdy
Registration No. 25,618

RLB/jhw
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528